REMARKS

The Invention

The presently claimed invention is based on the discovery of an antigenic sequence unique to *Chlamydia pneumoniae.* Accordingly, the invention is directed to methods for detecting *Chlamydia* in a sample by detecting the binding of an antibody specific to a peptide having a sequence consisting essentially of SEQ ID NO: 97.

The Office action

Claims 48 and 68-75 have been examined in the present Office action. Claims 70 and 73 are objected to and claims 48 and 68-75 stand rejected under 35 U.S.C. § 112, second paragraph and under 35 U.S.C. § 103(a). Each of these rejections and this objection is addressed below.

Objections to the Drawings

Applicants note that objections have been raised to the drawings; however, the Form PTO-948, referred to by the Examiner, was not included with the present Office action. Applicants therefore request that this form be mailed by the Office such that the appropriate drawing corrections can be made. Applicants further request that the present objection be held in abeyance pending receipt of a copy of this Form PTO-948.

Amendments to the Specification

As requested, Applicants have amended the specification to denote occurrences of trademarks.

Claim Objection

Claims 70 and 73 are objected to for being drawn to non-elected species. These claims have been cancelled, and this objection is therefore moot.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 48 and 68-73 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out the subject matter that Applicants regard as being the invention.

In particular, the Examiner finds that the claims fail to recite actual steps that would allow one skilled in the art to practice the invention, namely contact steps, detection steps, and correlation steps. As required by the Examiner, claim 48 has been amended to include such positive steps. As amended, claim 48 now requires providing an antibody that specifically recognizes a peptide having a sequence consisting essentially of SEQ ID NO: 97 and performing an *antigen-capture assay* such that binding of the antibody identifies a sample as being infected with *Chlamydia.* Antigen-capture assays involve the following steps: *contacting* a sample with a solid support on which antibodies

have been immobilized and *detecting* binding of the antibody to the sample such that the amount of an antigen in the sample is *assessed* by measuring the amount of antigen that is bound. Thus, claim 48 includes the positive steps outlined by the Office, by requiring that an antigen-capture assay be performed.

Contrary to the Examiner's assertion, this rejection should not apply to claims 68-73, which do in fact contain positive steps. Claim 68, from which claims 69 and 70 depend, includes the following steps: (a) providing a sample; (b) *contacting* the sample with a peptide having a sequence consisting essentially of SEQ ID NO: 97 (contact step); (c) *detecting* binding of an antibody in the sample to the peptide (detection step); and (d) *determining* whether *Chlamydia* is present in the sample based on binding of the peptide with anti-Chlamydial antibodies present in the sample (correlation step). Similarly, claim 71, from which claims 72 and 73 depend, includes the steps of: (a) providing an antibody that specifically binds to a peptide having a sequence consisting essentially of SEQ ID NO: 97; (b) immobilizing a sample to be tested onto a substrate; (c) *contacting* this immobilized sample with the antibody (contact step); and (d) *detecting* the presence of the immobilized antibody (detection step) wherein the presence of immobilized antibody indicates the presence of *Chlamydia* in the sample (correlation step). This aspect of the § 112 rejection may now be withdrawn.

The Examiner further finds that claims 48 and 68-73 are unclear for failing to recite how the antibodies are obtained and how such antibodies are to be detected in the

absence of a recitation of an antibody-associated label. In response to this rejection, claim 48 and claim 71 (from which claim 72 depends) have now been amended to include a step in which an antibody is provided.

Furthermore, with respect to the Office's assertion that claim 68 is unclear because it is unclear whether the sample already contains the antibody or whether the sample is to be contacted with the antibody, claim 68 (from which claims 69 and 70 depend) has been amended to specify that a peptide having a sequence consisting essentially of SEQ ID NO: 97 is provided to detect anti-*Chlamydial* antibodies in a sample. Support for this amendment is found, for example, at page 65, line 25 to page 67, line 15. No new matter has been added by this amendment.

With respect to the issue of how antibody binding is to be detected, the Office is directed to the discussion above, where Applicants point out that the present invention is based on the discovery of an antigenic sequence which allows the identification of *Chlamydia* in a sample. Applicants note that an artisan of ordinary skill seeking to practice the claimed invention at the time of filing would know how to detect the binding of antibodies to such antigenic peptides. In this regard, Applicants refer, for example, to page 16, lines 8-17 of the specification, which specifically teaches that the antibody may be labeled with an enzyme, fluorophore, radioisotope, or luminescer. Alternatively, the antibody may be covalently linked with a specific scavenger (e.g., biotin) such that detection results from binding with avidin or streptavidin labeled with an indicator

enzyme, fluorophore, radioisotope, or luminescer. Because one skilled in the art would recognize how to use the present methods using standard skills available in the art or taught in the specification, the claims are definite and this aspect of the rejection may be withdrawn.

Claims 68 and 71 are further rejected given the insufficient antecedent basis for recitation of the limitation "said sample." As required by the Examiner, claims 68 and 71 have now been amended to remove the term "said."

The Office further finds that claim 71, in reciting that the sample is immobilized onto a substrate, is unclear given that one skilled in the art would not know whether the entire sample is to immobilized and then contacted with the antibody or whether something else is intended. In response, claim 71 has been amended to clarify the claim language. This claim now requires that, a sample is first immobilized to a substrate, after which the *immobilized sample* is contacted with the antibody of the invention. Upon detection of the immobilized antibody, the sample is identified as being *Chlamydia* positive.

In view of the above, Applicants respectfully request that the § 112, second paragraph rejections be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 48 and 68-73 stand rejected under 35 U.S.C. § 103(a) as being obvious

over Kuroiwa *et al.* (EP 699,688; hereinafter "Kuroiwa") in view of Melgosa *et al.* (*Infection and Immunity* (1991) 59(6): 2195-2199; hereinafter "Melgosa").

As discussed above, claims 48, 68 (from which claims 69 and 70 depend), and 71 (from which claim 72 depends) are directed to methods for detecting *Chlamydia* in a sample by means of an antibody that specifically binds to a peptide having a sequence consisting essentially of SEQ ID NO: 97 or the peptide itself.

The Office asserts that Kuroiwa, in teaching methods and reagents useful for the detection of *Chlamydia* by means of monoclonal antibodies specific to Major Outer Membrane Proteins (MOMP), differs from the present invention only in failing to teach antibodies that bind specifically to a sequence of SEQ ID NO: 97. Turning to the second cited reference, the Office states that Melgosa teaches that the MOMP genes of several strains of *Chlamydia* are highly conserved and further discloses monoclonal antibodies specific to *Chlamydia pneumoniae* as well as the sequence of the claimed peptide. Relying on a combination of these references, the Examiner concludes that one skilled in the art would have been motivated to modify the methods taught by Kuroiwa to detect *Chlamydia* using antibodies which bind to highly conserved regions of *Chlamydia* species and thereby arrive at the claimed invention. For the reasons outlined below, Applicants respectfully traverse this rejection.

The standard for a *prima facie* case of obviousness is clearly set forth in MPEP § 2143.03, which states (emphasis added):

To establish a *prima facie* case obviousness of a claimed invention, *all the claim*

> *limitations* must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)

To this end, Applicants submit that, neither of the two cited references, alone or in combination, disclose all the limitations of the present claims. As is acknowledged by the Office, "Kuroiwa does not teach the binding of a peptide consisting of SEQ ID NO: 97." Applicants submit that the second cited reference does not cure this deficiency. Although the Examiner states that Melgosa teaches the sequence of the claimed peptide, nowhere in the reference is the existence of an antigenic peptide taught or suggested. Contrary to the Examiner's assertion, Melgosa only goes so far as to teach the *complete* sequence of the *Chlamydia pneumoniae* MOMP structural gene and its predicted amino acid sequence. Applicants assert that knowledge of the *entire* sequence of the MOMP gene does not suggest the presence, location, or existence of a useful antigenic sequence, much less the particular antigenic sequence (SEQ ID NO: 97) that is central to the presently claimed invention. Accordingly, one skilled in the art, based on the teachings of Kuroiwa and Melgosa, would not have been able to practice the invention as claimed. The claimed invention cannot be obvious given that neither of these references disclose or suggest methods of detecting *Chlamydia* in a sample using Applicants' antigenic sequence. Absent such a suggestion, teaching, or motivation *in the prior art*, no *prima facie* case of obviousness has been established, and the § 103(a) rejection should be withdrawn.

CONCLUSION

Applicants hereby submit that the claims are now in condition of allowance and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including October 23, 2003, and a check in payment of the required extension fee.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 23 October 2003

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50321.002002 Reply to Office Action mailed on 04.23.031.doc